OBJ_DOKU-184978-002.fm Seite 1 Montag, 12. Dezember 2011 3:57 15

Notes on use

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Ignition Adapter for ESU/APC™

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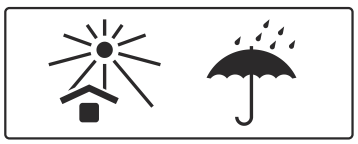

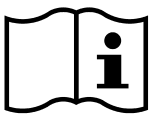

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OBJ_DOKU-184978-002.fm Seite 2 Montag, 12. Dezember 2011 3:57 15

Table of Contents

IMPORTANT! **3**
1 Intended Use **3**
2 Safety Instructions **3**
3 How to Use **4**
3.1 Check the product 4
3.2 Ignition test 4
3.3 What should you do if the argon plasma does not ignite? 5
4 Cleaning, Disinfection, Sterilization **6**
4.1 Safety Instructions 6
4.2 Reconditioning Limitation 6
4.3 Recommended Processing Agents/Equipment 7
4.4 Recommended Methods 7
4.5 Required Aids 7
4.6 Precleaning 8
4.7 Manual Cleaning and Disinfection 8
4.8 Cleaning and Disinfection by Machine 9
4.9 Check 10
4.10 Packaging 10
4.11 Sterilization 10

OBJ_DOKU-184978-002.fm Seite 3 Montag, 12. Dezember 2011 3:57 15

IMPORTANT!

Please read all information carefully.

These notes on use do not replace the user manual of the APC unit and Electrosurgical unit used! Read the user manuals of the APC unit and Electrosurgical unit and ask ERBE or your distributor in case of doubt!

1 Intended Use

The Ignition Adapter for ESU/APC[1)] is intended to perform an ignition test with flexible ERBE APC probes.

The Ignition Adapter can only be used on the following ERBE Elektromedizin units:

- ElectroSurgical Unit (ESU) ICC 200 or 350 in conjunction with an Argon Plasma Coagulator Model APC 300™.
- ESU VIO® Model in conjunction with an Argon Plasma Coagulator Model APC 2.

2 Safety Instructions

WARNING!

This product may only be used by medical personnel who have been trained per these instructions.

Before each use, check that the product is intact, including all the insulation. Verify that there are no signs of physical damage.

If damaged, do not use this product!

1.) In User Manuals the Ignition Adapter for ESU/APC is referred to as tester.

Do not use in the presence of combustible or explosive materials!

Protect this product from any form of mechanical damage! Do not throw! Do not use force!

ERBE Elektromedizin expressly warns against modifying the product. Any modification exempts ERBE Elektromedizin from any and all liability.

3 How to Use

Clean/disinfect and/or sterilize this product before using it for the first time and before every subsequent use.

3.1 Check the product

Before each use, check that the product is intact, including all the insulation. Verify that there are no signs of physical damage.

If damaged, do not use this product!

3.2 Ignition test

Before and during the ignition test do not touch any non-sterile objects with the the APC probe.

You must not touch the Ignition Adapter or the beam (plasma stream) during the testing.

Do not ignite/fire the APC probe at the Ignition Adapter for longer than 5 seconds. Continuous activation or several consecutive activations may damage the Ignition Adapter or APC probe.

For ESU ICC Models: Only use the neutral electrode settings “split neutral electrode (‖)” or “any neutral electrode (| ‖)”.

OBJ_DOKU-184978-002.fm Seite 5 Montag, 12. Dezember 2011 3:57 15

1. Switch on unit(s).
2. Select the following unit settings on the ESU:
   - On VIO Models: FORCED APC®, 25 – 50 Watt
   - On ICC 350: SPRAY COAG, 40 – 60 Watt
   - On ICC 200: APC-Mode (coded for by Display A. + two digits for the power), 40 – 60 Watt
3. Connect the APC probe to the Argon Plasma Coagulator.
4. Plug the Ignition Adapter into the NE receptacle on the ESU.
5. Press the Purge button of the Argon Plasma Coagulator.
6. Hold the tip of the the APC probe at a distance of 1 – 4 mm toward the middle of the Ignition Adapter.
7. Depress the blue pedal of the footswitch to activate the APC probe. A plasma stream should form between the probe and Ignition Adapter. If it does not, please read the next section.

Once the plasma has ignited, it normally ignites without delay for subsequent activations.

8. Now connect the neutral electrode to the ESU.

3.3 What should you do if the argon plasma does not ignite?

1. Check the argon flow. Is it sufficient?
2. Check all the connections. Are they okay (intact and secure)?
3. Inspect the tip of the APC probe. Is it burned off, plugged, or soiled? If possible clear the obstruction or use a new APC probe.

OBJ_DOKU-184978-002.fm Seite 6 Montag, 12. Dezember 2011 3:57 15

4 Cleaning, Disinfection, Sterilization

To ensure that cross contamination doesn't take place, the product may need to be cleaned, disinfected, and/or sterilized. For example, in a situation where the Adapter has come into contact with biohazardous contaminant(s) like blood or other bodily fluids, disinfection wiping may not be adequate. In this case, follow the reprocessing instructions below.

4.1 Safety Instructions

ERBE Elektromedizin recommends machine cleaning/ disinfection.

On no account use sharp or abrasive objects for cleaning purposes.

It is essential to follow the cleaning agent and disinfectant manufacturers' instructions.

Disinfectants must be rinsed off thoroughly after use!

The product can be cleaned/disinfected up to a maximum temperature of 203 °F (95 °C).

The product can be sterilized up to a maximum temperature of 280 °F (138 °C).

Do not sterilize in hot air oven!

4.2 Reconditioning Limitation

Frequent reconditioning can damage this product. Observe the safety instructions for checking the product. With visible damage or functional impairment, the product may no longer be used.

OBJ_DOKU-184978-002.fm Seite 7 Montag, 12. Dezember 2011 3:57 15

4.3 Recommended Processing Agents/Equipment

The listed cleaning/disinfection agents and sterilization equipment have been validated with the following processing procedures.

- Manual cleaning/disinfection with the detergent Cidezyme ® LF/Enzol and disinfectant Cidex ® OPA (Johnson & Johnson Medical Limited, Gargrave, Skipton).
- Machine cleaning and disinfection in a G 7836 CD disinfector (Miele & Cie. KG, Gütersloh, Germany) with the cleaning agent neodisher ® mediclean forte (Dr. Weigert GmbH & Co. KG, Hamburg, Germany) with the recommended washing program.
- Autoclave.

4.4 Recommended Methods

ERBE recommends the preparation procedures described below. Equivalent different procedures are possible if not explicitly excluded. It is incumbent on the user to ensure the suitability of the actual procedures used by means of suitable measures (e.g. validation, routine monitoring, check of material compatibility).

4.5 Required Aids

Reprocessing step	**Items Needed**
Precleaning	Soft cloth
Manual cleaning/disinfection	Soft disposable cloth (lint-free)
	Compressed air gun (2 bar maximum)

4.6 Precleaning

Use water for precleaning, a non-fixing disinfectant if necessary.

1. Remove surface contaminants with a soft cloth. To do so, place the product in a water bath and/or rinse the product under running water.

4.7 Manual Cleaning and Disinfection

Use a liquid detergent suitable for soaking.

Use a disinfectant compatible with the detergent suitable for soaking.

If not otherwise specified, use water for rinsing which is at least of drinking water quality.

Only disinfect clean products that have dried slightly.

1. Prepare a cleaning bath according to the manufacturer's directions.
2. Place the product in the bath so that the surface is completely covered. In doing so also make sure the product is not touching other instruments or parts of instruments. Comply with the recommended action (soaking) time.
3. If necessary, clean off any remaining contaminants from the product with a clean soft cloth.
4. Carefully remove the product from the bath.
5. Rinse the product thoroughly (for at least 1 minute) under flowing water.
6. Dry the product with compressed air.
7. Prepare a disinfectant bath according to the manufacturer's directions.
8. Place the product in the bath so that the surface is completely covered. In doing so also make sure the product is

not touching other instruments or parts of instruments. Comply with the recommended action (soaking) time.

9. Carefully remove the product from the bath.
10. Rinse the product thoroughly (for at least 1 minute) with sterile deionized water.
11. Dry the product with compressed air.

4.8 Cleaning and Disinfection by Machine

The washer/disinfector must have fundamentally certified effectiveness (e.g. CE marking according to DIN EN ISO 15883).

The detergent and disinfectant must be suitable for medical devices made of plastic and metal and have a pH value between 5.5 and 11.

If highly alkaline cleaners are used, metal surfaces may be discolored. However, this does not affect the integrity of the product.

It is essential to follow the cleaning agent and disinfectant manufacturers' instructions.

1. Place the product in a suitable rinsing basket carefully. In doing so make sure the product is not touching other instruments or parts of instruments.
2. Connect the product to a rinsing station.
3. Start a tested program with the following properties:
   - Thermal disinfection (5 to 10 minutes at 194 to 199 °F [90 to 93 °C]).
   - Final rinse with distilled or deionized water.
   - Sufficient product drying.
4. Repeat the machine cleaning/disinfection process if the product still shows visible contamination after the program has ended.

4.9 Check

1. Check the product for visible damage and wear:
   – Damage to the product, e.g. cracks, rough surface, splintering.
   – Damage to the product insulation and/or cable/connector insulation, e.g. cracks and breaks.

If damaged, do not use this product!

4.10 Packaging

1. Pack the product in disposable sterilization packaging (single or double packaging) made from paper/polyethylene and/or in a sterilization container.

4.11 Sterilization

Only sterilize products that have been cleaned and disinfected.

ERBE Elektromedizin recommends steam sterilization with the method described below. If other sterilization methods are used, ERBE Elektromedizin shall bear no responsibility.

Steam sterilization

- Pre-vacuum method with adequate product drying
- Holding time 3 to 18 minutes at 270 to 273 °F (132 to 134 °C)
- Sterilizers in accordance with applicable national standards and regulations (e.g. DIN EN 13060 or DIN EN 285)
- Sterilization process validated according to DIN EN ISO 17665

Please follow the recommendations issued by the sterilizer manufacturer concerning loading, handling, etc.

OBJ_DOKU-184978-002.fm Seite 11 Montag, 12. Dezember 2011 3:57 15

OBJ_DOKU-184978-002.fm Seite 12 Montag, 12. Dezember 2011 3:57 15

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